

Decision Memo for Clinical Trial Policy (CAG-00071R2)

Decision Summary

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Decision Memo

TO: Administrative File: CAG-00071R2
Clinical Trial Policy

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SUBJECT: Decision Memorandum for the Clinical Trial Policy

DATE: October 17, 2007

On July 19, 2007, CMS opened a second reconsideration of the Clinical Trial Policy (CTP) National Coverage Determination (NCD) and issued a proposed decision memorandum. The proposed decision included standards that we believe are necessary for the protection of subjects in research studies and other standards, an approval process to determine if a study met those standards, and proposed to clarify the items and services that would be covered in approved trials. We have received numerous comments that continue to question the authority of CMS to establish standards and provide limitations to coverage within research studies. Moreover, some commenters were confused by some aspects of the proposed policy and suggested that CMS should use notice and comment rulemaking in order to provide a longer transition period for clinical trials to prepare for these changes.

Following the expiration of the public comment period, Congress passed the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85 (September 27, 2007). The new legislation establishes significant requirements for clinical trials and additional authority for other agencies in the Department of Health and Human Services. CMS is continuing to review this new legislation and will work with other HHS components in order to avoid imposing duplicative or inconsistent obligations. Thus, after careful consideration, the Agency has decided that no change to the July 9, 2007 policy is appropriate at this time and therefore, we are not imposing any additional conditions of coverage.

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